

REMARKS

Claims 22-44 are pending. Claims 22, 35-38 and 43-44 have been canceled without prejudice or disclaimer of the subject matter recited therein, and applicants reserve all rights to such subject matter. The office action is addressed below.

35 USC §112 - Enablement

The Examiner rejects all pending claims under 35 USC §112, first paragraph as allegedly non-enabled for certain embodiments. The Examiner asserts that the specification is enabling for claims directed to "A nucleic acid sequence encoding at least one autonomously folding polypeptide domain or at least one immunogenic polypeptide, wherein the sequence comprises a linear concatamer of at least two non-identical DNA sequences, wherein the non-identical DNA sequence each encodes the same amino acid sequence coding for the autonomously folding polypeptide domain or the polypeptide." The Examiner also asserts that the specification is enabling for pharmaceutical compositions of the above described sequences as well as methods of delivering such compositions.

Without acquiescing in rejection, Applicants have amended the claims above to recite those embodiments.

The Examiner also asserts that the specification is not enabling for pharmaceutical compositions containing linear concatamers of nucleic acid sequences for use as a drug. The Examiner, however, has indicated that the specification is enabling for pharmaceutical compositions comprising nucleic acid sequences encoding autonomously folding polypeptide domains or immunogenic polypeptides. As described above, and without acquiescing in the rejection, the claims have been amended to recite such sequences and therefore this enablement rejection should be withdrawn, as well.

35 USC §112 - Indefiniteness

The Examiner rejects all pending claims under 35 USC §112 as allegedly indefinite due to a number of grammatical errors. Without acquiescing to the merits of the rejections, the claims have been amended and each rejection overcome.

35 USC §102 - Anticipation

The Examiner has rejected claims 22, 24, 30, 31, 32, 41, and 42 under 35 USC §102(b) as allegedly anticipated by Ferrari *et al.* (US Pat No. 5,641,648). Without acquiescing to the merits of the rejection of these claims, claim 22, as noted above, has been cancelled and all claims pending from claim 22 have been amended to depend from claim 23. Applicants note with appreciation that the Examiner considers claim 23, as well as claim 29, free of the cited prior art. In view of the above amendments, applicants assert that all remaining claims are free of the cited prior art and respectfully request the withdrawal of this rejection.

35 USC §103(a) - Obviousness

The Examiner rejects claims 22, 24, 30, 31, 32, 41, and 42 under 35 USC §103(a) as allegedly obvious over any of Matsunaga (US Pat No. 5,861,285, Eilers *et al.* (US Pat No. 6,265,562) and Whitlow (US Pat No. 5,767,260) taken with Ferrari *et al.* (US Pat No. 5,641,648).

Again, without acquiescing to the merits of the rejection, as noted above, claim 22 has been cancelled and all the claims depending therefrom have been amended to depend from claim 23. Accordingly, applicants assert that all remaining claims are free of the cited prior art and respectfully request the withdrawal of this rejection.

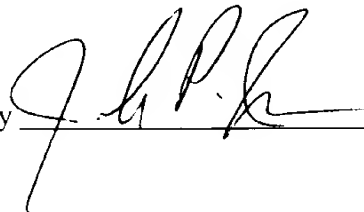
CONCLUSION

In view of the above amendments and arguments, Applicants respectfully request the withdrawal of all rejections of the pending claims and that the case be passed to allowance.

Respectfully submitted,

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By



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23. (Amended) A nucleic acid sequence encoding at least one autonomously folding polypeptide domain or at least one immunogenic polypeptide having [at least] greater than 30 amino acids, wherein the sequence comprises a linear concatamer of at least two non-identical DNA sequences, wherein the non-identical DNA sequences each encode the same amino acid sequence of [a] said autonomously folding polypeptide domain or immunogenic polypeptide that is a ligand of complement receptor type 2 (CR2, CD21), and wherein the concatamer comprises [codes for] a sequence encoding an oligomer of the autonomously folding polypeptide domain or immunogenic polypeptide in a continuous reading frame.
24. (Amended) [A] The nucleic acid sequence according to claim [22] 23, wherein a single invariant cysteine codon has been added to [one] a DNA sequence to encode a polypeptide derivative with a unique unpaired cysteine.
25. (Amended) [A] The nucleic acid sequence according to claim 24, wherein the added cysteine codon is located at the 3' end of the sequence to encode a cysteine at the C-terminus of the [corresponding] polypeptide derivative.
26. (Amended) [A] The nucleic acid sequence according to claim [22] 23, wherein the concatamer is fused to one or more sequences encoding one or more antigens.
27. (Amended) [A] The nucleic acid sequence according to claim [22] 23, wherein the concatamer is fused to one or more sequences encoding one or more antigens and a single cysteine codon has been added to or inserted in-frame in only one antigen coding sequence.
28. (Amended) [A] The nucleic acid sequence according to claim 26, wherein the concatamer is fused to one sequence coding one antigen.

29. (Amended) **[A] The** nucleic acid sequence according to claim **[22] 23**, wherein the encoded polypeptide **[ligand]** is the complement C3 fragment Cad, or a sub-fragment thereof.
30. (Amended) An expression vector comprising a concatamer nucleic acid sequence according to claim **[22] 23** and regulatory or other sequences for expression of any oligomeric polypeptide encoded thereby.
32. (Amended) A method of making a concatamerised polypeptide, the method comprising expressing a concatamer according to claim **[22] 23** in a host cell; and isolating the expressed product.
41. (Amended) A pharmaceutical composition comprising a concatamer according to claim **[22] 23** and a physiologically acceptable excipient or carrier.